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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,637	05/02/2001	Yaakov Naparstek	13125-002001 / 6433/US/99	6610

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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/16/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,637

Applicant(s)

NAPARSTEK ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-83 is/are pending in the application.
- 4a) Of the above claim(s) 4,8-12,14,17-23 and 36-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,13,15,16 and 25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 6/26/03 (Paper No. 20), is acknowledged.

Claim 24 has been cancelled.

Claims 28-83 have been added.

Claims 1-3, 5, 7, 13, 16 and 25-27 have been amended.

Claims 1-23 and 25-83 are pending.

Claims 4, 8-12, 14, 17-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

Newly submitted claims 36-83 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 36-72 are drawn to various methods of use of the peptides, however the methods as recited may be practiced with other materially different products. For example, a method of treating the autoimmune disease rheumatoid arthritis may be practice with methotrexate and antibodies may be produced by immunizing with any of a number of peptides. Claims 73-83 are drawn to the invention of Group VII set forth in Paper No. 13.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-83 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-3, 5-7, 13, 15-16 and 25-35 are under consideration in the instant application.

Applicant's request for rejoinder of the method claims is acknowledged, but is held in abeyance in view of the rejection set forth herein.

2. Applicant's amendment, filed 6/26/03 has obviated the rejections of record in Paper No. 17 by limiting the peptides to those in which the peptide sequence does not extend beyond that set forth in either SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3.

3. The following are New Grounds of Rejection.

Claim Rejections - 35 USC § 112 first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-7, 13, 15-16 and 25-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein. *This is a New Matter rejection for the following reasons:*

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Applicant's amendment asserts that no New Matter has been added. Applicant notes that the specification discloses peptide sequences "comprising SEQ ID NO:2 or 3", and argues that since SEQ ID NO:2 and SEQ ID NO:3 are each internal fragments of SEQ ID NO:1 this provides adequate written support for the newly added limitation in claim 1 in which the peptide "consists of part or all of SEQ ID NO:1, wherein the sequence comprises SEQ ID NO:2 or SEQ ID NO:3". Applicant also notes that the specification on page 3 at lines 2-8 describes "biologically functional homologues and derivatives" of SEQ ID NOS: 1, 2 or 3 and that page 5 at lines 7-13 notes that this includes deletions, substitutions and insertions which do not alter biological activity.

The language of instant claim 1 is drawn to a subgenus of peptides contained within the genus of peptides that are "all or part of SEQ ID NO:1". It is acknowledged that SEQ ID NO:2 and SEQ ID NO:3 are two species within this genus. SEQ ID NO:1 is a 22 amino acid sequence that contains within it SEQ ID NO:2 (the amino terminal 16 amino acids) and SEQ ID NO:3 (the carboxy terminal 16 amino acids).

However, the specification does not appear to provide an adequate written description of the subgenus of peptides as set forth in claim 1.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

In the instant case, the specification does not appear to set forth the subgenus as now claimed. Although the specification mentions peptides comprising SEQ ID NO:2 or comprising SEQ ID NO:3, there does not appear to be a description of those peptides limited to SEQ ID NO:1. Similarly, although deletions of SEQ ID NO:1 are mentioned, there does not appear to be a description of those deletions that define a subgenus comprising SEQ ID NO:2 or SEQ ID NO:3.

Similarly, instant claim 28 is drawn to a subgenus of peptides that are fragments of either SEQ ID NO:2 or SEQ ID NO:3, but that comprise a subsequence defined by amino acids 7-16 of SEQ ID NO:1. Thus claim 28 also attempts to define a subgenus based upon the disclosure of a genus (e.g., peptides that are all or part of SEQ ID NO:2) and a single species (the peptide defined by residues 7-16 of SEQ ID NO:1). It is further noted that although mention is made of a common motif shared between peptide 6 (SEQ ID NO:2), peptide 7 (SEQ ID NO:3) and another peptide, this motif is set forth as amino acid residues 18-22 of SEQ ID NO:9. The motif defined by residues 7-16 of SEQ ID NO:1 is a particular species of this motif.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Obviousness is not the standard for the addition of new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). New Matter is a written description issue.

The dependent claims are included in this rejection because although some of the dependent claims limit the scope of the independent claim to a particular species, the language of the independent claim which is New matter is necessarily present in each dependent claim.

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Drawings

6. The formal drawings filed 6/26/03 have been approved by the Draftsman.

Conclusion

7. No claim is allowed.

8. Peptides consisting of SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3 each appear to be free of the art.

9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
September 15, 2003

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9/15/03